

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the claims

Claims 1-19, 22-42 were previously withdrawn, and claims 20, 21 and 44 were previously cancelled.

Claim 43 is amended. The amendment to claim 43 is supported by the English-language specification at page 9, lines 30-37, which recites:

E. coli that has a plasmid pIBIBSF2R containing cDNA encoding human IL-6 receptor has been internationally deposited under the provisions of the Budapest Treaty as HB101-pIBIBSF2R on Jan. 9, 1989 with the National Institute of Bioscience and Human Technology, Agency of Industrial Science and Technology, of 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki pref., Japan, as FERM BP-2232.

No new matter is added. This amendment is made solely to advance prosecution and not in acquiescence to any rejection.

After the foregoing amendments, claims 1-19, 22-43 and 45-47 are pending, with claims 43 and 45-47 under examination.

II. New matter rejection under 35 U.S.C. § 112, first paragraph

At items 5 and 5a, pages 2-4 of the Office Action, claims 43 and 45-47 are rejected for attempting to incorporate subject matter which is alleged to be new matter. Applicants respectfully traverse. Solely to advance prosecution, however, claim 43 is amended to remove the language which forms the basis for the rejection, and replaced with language that is recited in the specification. Applicants respectfully believe that the rejection is overcome and request its withdrawal.

III. Enablement rejection under 35 U.S.C. § 112, first paragraph

At item 5b, pages 4-5 of the Office Action, claims 43 and 45-47 are rejected for allegedly “not reasonably provid[ing] enablement for a method of treating all inflammatory diseases by administering ‘all’ interleukin-6 antibodies.” Office Action at page 4. Applicants respectfully traverse both aspects of the rejection.

As to the first aspect of the rejection, claim 43 does not claim a method of “treating all inflammatory diseases,” as asserted, but the considerably more defined scope of a “method of treating *inflammatory bowel disease*” (emphasis added). Properly construed, this aspect of the claim is commensurate with the enablement provided by the specification.

The second aspect of the rejection, concerning “all” interleukin-6 antibodies, relies on a construction of claim 43 such that it reads not only on antibodies against the IL-6 receptor, *per se*, but also gp130. This issue is respectfully believed to be overcome by the amendment to claim 43. Amended claim 43 recites an “anti-interleukin-6 receptor antibody which binds to human interleukin-6 receptor encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232.” As described in English-language specification at page 9, lines 30-37, FERM BP-2232 contains DNA which encodes the human IL-6 receptor. Therefore, claims 43 and 45-47 read on antibodies which bind to the IL-6 receptor, *per se*.

Applicants respectfully believe that the rejection is overcome and should be withdrawn.

IV. Rejections under the indefiniteness provision of 35 U.S.C. § 112, second paragraph.

At points 6 and 6a, pages 5-6, claims 43 and 45-47 are rejected under 35 U.S.C. § 112, second paragraph. The rejections of claims 45-47 relies on their dependence from claim 43, which is rejected for two reasons. The first reason, based on the recitation of “having the following amino acid sequence,” is rendered moot by the amendment to claim 43 which cancels this language.

The second reason is that “the biological activity of IL-6” is alleged to have insufficient antecedent basis. Applicants respectfully traverse. As noted in MPEP

§ 2173.05(e), “the mere fact that the body of a claim recites additional elements which do not appear in the claim’s preamble does not render the claim indefinite.” Furthermore:

Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Energizer Holdings Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006)(holding that "anode gel" provided by implication the antecedent basis for "zinc anode"); *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid"). Inherent components of elements recited have antecedent basis in the recitation of the components themselves.

Id. The property of “inhibits the biological activity of IL-6” is reasonably ascertainable to those skilled in the art and, hence, is not indefinite. This is especially so when read in the context of the entire claim 43, which recites a method comprising administering an “anti-interleukin-6 receptor antibody” which has the properties of (a) binding to human interleukin-6 receptor encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232 (b) blocking signal transduction by IL-6 and (c) inhibiting the biological activity of IL-6. That is, “inhibits the biological activity of IL-6” is one of the several recited properties of the anti-interleukin-6 receptor antibody used in the claimed method.

In another sense, the recitation of “inhibits the biological activity of IL-6” is an element that is inherently present when the “anti-interleukin-6 receptor antibody” recited in claim 43 binds to the human interleukin-6 receptor. It is understood that a receptor binds a ligand and, through the process of signal transduction, causes a biological response. Conversely, inhibition of a receptor may, in some cases, inhibit the biological activity of the ligand. It is therefore understood in view of the specification that “inhibits the biological activity of IL-6” is inherently present in recitation of the specific IL-6 receptor inhibitor, earlier in claim 43. It follows that “inhibits the biological activity of IL-6” does have antecedent basis in the claim, such that its recitation is not vague and indefinite.

Applicants respectfully believe that the rejection has been overcome in regards claim 43 and, accordingly, dependent claims 45-47. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. Rejection under 35 U.S.C. § 102

At items 7 and 7a, pages 6-7, it is asserted that claims 43 and 45-47 are anticipated by WO 96/38481, which allegedly discloses antibodies which bind to, and inhibit, gp130. Applicants respectfully traverse the rejection but, solely to advance prosecution, have amended claim 43. Pending claim 43 reads on antibodies against IL-6 receptor, *per se*. WO 96/38481 does not disclose a method of treating inflammatory bowel disease comprising administering to a subject in need thereof an anti-interleukin-6 receptor antibody which binds to human interleukin-6 receptor encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232, blocks signal transduction by IL-6 and inhibits the biological activity of IL-6. WO 96/38481 does not anticipate claims 43 and 45-47, therefore.

Applicants respectfully believe that the rejection is overcome and request its reconsideration and withdrawal.

VI. Rejection under 35 U.S.C. § 103

At items 8 and 8a, pages 7-8, it is alleged that claims 43 and 45-47 are rendered obvious by the combination of WO 96/38481 with Queen *et al.*, U.S. Patent No. 5,530,101. Applicants respectfully traverse because neither reference, or their combination, discloses or even suggests a method of treating inflammatory bowel disease comprising administering to a subject in need thereof an anti-interleukin-6 receptor antibody which binds to human interleukin-6 receptor encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232, blocks signal transduction by IL-6 and inhibits the biological activity of IL-6.

Applicants respectfully believe that the rejection is overcome and request its reconsideration and withdrawal.

CONCLUSION

Applicants believe that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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